



VIA EFS

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In Re Patent Application of:  
Henrich Cheng

Conf. No.: 2231 : Group Art Unit: 3734  
Appln. No.: 10/766,530 : Examiner: Michael G. Mendoza  
Filing Date: January 29, 2004 : Attorney Docket No.: 681942-1US  
: (HC0001US)

Title: METHOD AND MIXTURE FOR NERVE ROOT REPAIR

**DECLARATION OF HENRICH CHENG UNDER 37 C.F.R. § 1.132**

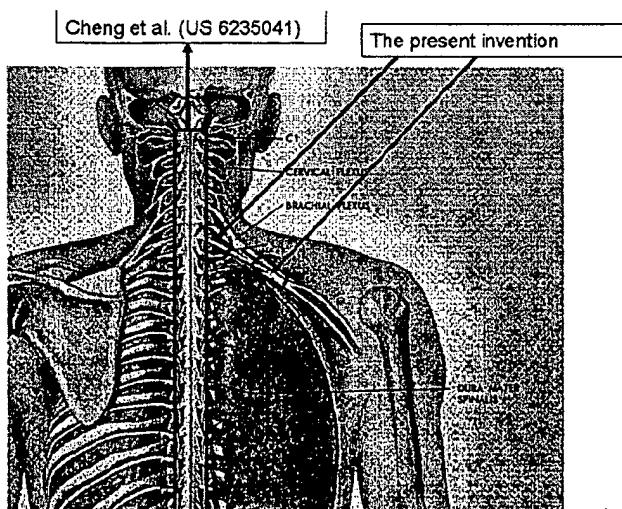
I, Henrich Cheng, hereby declare as follows:

1. I am the inventor of the invention described and claimed in patent application No. 10/766,530 (hereinafter '530 App). I am employed as Chief of Center for Neural Regeneration at Taipei Veterans General Hospital, Taiwan, R.O.C., and a professor in the Department & Institute of Pharmacology, School of Medicine, National Yang-Ming University at Taiwan, R.O.C. My current research focuses on repair of spinal cord and nerve roots after trauma and neural regeneration and trophic factor. Please refer to my C.V. as shown in Schedule A, which shows my education, experience, awards, and relevant publications and patents. Based on the foregoing, I believe that I qualify as an expert and am considered by others to be an expert in the field and science mentioned above.
2. I am familiar with the '530 App, and have reviewed the Office Action mailed on July 21, 2008 on the '530 App. The '530 App is based on a new method of functionally connecting a portion of the peripheral nervous system to a portion of the central or peripheral nervous system of a vertebrate by applying to the gap with a fibrin glue mixture, comprising a growth factor, fibrinogen, aprotinin and divalent calcium ions, which is supported by such as Example 1 and Example 4 of the '530 App.

3. As shown in Example 1 of the '530 App (on page 10), rats having paralysis of the hand muscles, which were repaired by the method of the present invention, showed signs of recovery two or three weeks later. Two months postoperatively, the group's ability to freely move the left elbow progressed, as well as their ability to fully extend claws while reaching and their ability to bear weight.

4. As showed in Example 4 of the '530 App (on page 13), the rats had a transected 15 mm nerve removed, and fibrin glue mixtures containing and not containing 1  $\mu\text{g}/\mu\text{l}$  aFGF were applied to the gap. Eight weeks postoperatively, the lesion degree was evaluated by the Sciatic Function Index (SFI), and the rats receiving the repair method of the present invention (fibrin glue mixtures containing 1  $\mu\text{g}/\mu\text{l}$  aFGF) had higher scores, which means a better recovery. Altogether, the invention is based on the discovery that avulsions between the central and peripheral nervous systems can be repaired using a fibrin glue mixture containing 1  $\mu\text{g}/\mu\text{l}$  aFGF as claimed to restore the functional connection of the avulsed ends.

5. Based on my knowledge and being the primary inventor of Cheng et al. (US 6235041), I am sure that the present invention is quite different from Cheng et al. for the following reasons. In Cheng et al. (US 6235041), the invention as claimed deals with the repair of different nerve regions. Cheng et al. provides a medical device of a biocompatible material for use in the treatment for a gap or defect in the central nervous system and adapted to enable connection of nerve fibers of gray and white matter between the proximal end and distal end thereof in predetermined openings (see Abstract). However, the present invention provides a method of functionally connecting a portion of the peripheral nervous system and a portion of the central or peripheral nervous system. Please refer to the diagram (Fig.1) below for demonstration.



The rectangle is the spinal cord, where the medical device of Cheng et al. was applied, and the two circles represent the positions (the junction of spinal nerves and peripheral nerves or peripheral nerves themselves) where the present invention is applied. The invention disclosed in Cheng et al. is different from the invention claimed in the '530 App, because of the repair of different regions of nerves.

6. It is well known that the central nerve system is made up of the spinal cord and brain. Both the spinal cord and brain contain "white matter" and "gray matter," wherein white matter is bundles of axons coated with a sheath of myelin, and gray matter is masses of cell bodies and dendrites. Each pair of spinal cord nerves is "mixed" nerves, containing sensory and motor axons. However, peripheral nerves are not "mixed" nerves, and neither sensory nor motor nerves contain "white matter" and "gray matter." Cheng et al. only dealt with the connection of a break of the spinal cord. More particularly, Cheng et al. provides a device and method for connecting the "gray matter" and "white matter" in the spinal cord. The '530 App provides a method for connecting the spinal cord and a peripheral nerve (i.e., nerve root) or for repairing the gap or defect in the peripheral nerve with the fibrin glue mixtures containing aFGF, and it has nothing to do with white matter and gray matter. Because of the different structure and function between the spinal cord or the central nerves on the one hand, and the peripheral nerves on the other hand, there is no way to expect either the medical device or the fibrin glue composition as claimed in Cheng et al. to work on peripheral nerve system. Careful and meaningful experimentation was necessary to invent the subject matter claimed in the '530 App. Given the above, the present invention was not and would not have been obvious over Cheng et al.

7. Schenck et al. (US 4553542, "Schneck") is related to an encircling device by which anatomical structures, such as the outer nerve sheaths, are being anastomosed. But throughout the specification of Schenck, there is neither a description of the definition of "nerves" nor examples showing the success in the recovery in function after the suture for the anastomoses. As mentioned above, "nerves" in different regions have different functions and structures. Schenck neither taught nor suggested the connection between the spinal cord and a peripheral nerve (i.e., nerve root) or a break of a peripheral nerve with the fibrin glue mixtures containing aFGF. Moreover, there is no functional recovery data among the embodiments of Schenck. Even though the nerve sheaths were anastomosed by the device of Schenck, there was still no evidence to show that the nervous repair was successful in functional recovery. Therefore, the present invention would not have been obvious over Cheng et al. in view of Schenck.

Application No. 10/766,530

5. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the above-identified application or any patent issued thereon.

Date: 208222 By: Henrich Cheng

Henrich Cheng

Schedule A

*Curriculum Vitae*

**Henrich Cheng M.D., Ph.D.**

Chief, Center for Neural Regeneration, Taipei Veterans General Hospital  
Professor, Dept. & Inst. Pharmacology, School of Medicine, National Yang-Ming  
University  
Chairman, Taiwan Neurospinal Society

**Education:**

1993-1996 **Karolinska Institute. Ph.D. in Neuroscience**  
Stockholm, Sweden  
1975-1983 **National Yang-Ming University. Doctorate degree in Medicine**  
Taipei, Taiwan

**Professional Experience:**

2007 **Professor of Brain Research Center**  
Department of Medicine, National Yang-Ming University  
Taipei, Taiwan  
2006 **Professor of Pharmacology**  
Department of Medicine, National Yang-Ming University  
Taipei, Taiwan  
2005 **Visiting Professor**  
Department of Neurological Surgery, University of California, Davis  
California, USA  
2002-2006 **Chief of the Neural Regeneration Center**  
1997-2003 **Neural Regeneration Laboratory Chief of Staff**  
Neurological Institute, Taipei Veterans General Hospital  
Taipei, Taiwan  
**Associate Professor of Surgery**  
Department of Medicine, National Yang Ming University  
Taipei, Taiwan  
**Visiting Associate Professor**  
Department of Neuroscience, Karolinska Institute  
Stockholm, Sweden  
1998-2002 **Visiting Professor**  
Barrow Neurological Institute  
Phoenix, Arizona, USA.  
1990-2001 **Attending Physician**  
Department of Neurosurgery, Taipei Veterans General Hospital  
Taipei, Taiwan  
1990-1997 **Lecturer**  
Surgery Section, Department of Medicine  
National Yang Ming University  
Taipei, Taiwan  
1985-1990 **Teaching Assistant**  
Surgery Section, Department of Medicine  
National Yang-Ming University, Taipei Veterans General Hospital  
Taipei, Taiwan

## Awards:

2008	<b>Outstanding Professor</b> Elected by students on campus National Yang-Ming University
2007	<b>Outstanding Medical Contribution</b> National Yang-Ming University
2007	<b>Leading Innovation on Medical Technique and Treatment</b> Taipei Veterans General Hospital, Taiwan, ROC
2006	<b>Leading Health Professionals of the World</b> International Biographical Center, Cambridge, England
2004	<b>First Outstanding Alumnus</b> National Yang-Ming University Award
2003	<b>Outstanding Physician</b> Veterans Affairs Commission, Executive Yuan, ROC
2003	<b>Outstanding Research &amp; Development</b> <b>Strategies for Neural Regeneration: Growth Factor Cocktail Therapy, Olfactory Ensheathing Cell, and Neuroprotective Gene Therapy</b> Veterans Affairs Commission, Executive Yuan, ROC
2003	<b>Certificate of Achievement Award</b> 10 <sup>th</sup> Sino-Japan Symposium on Cancer Treatment, Taiwan
2001	<b>Christopher Reeve Paralysis Foundation</b> Research Grants Program Award
2001	<b>Nominated for Best Hospital Structure Recommendation: Spinal Cord Injury Repair Strategy</b> The Executive Yuan of the Republic of China
1999	<b>Erenst Bors Society Research Award</b> California, USA
1997-1998	<b>Medical Innovation Award</b> Taipei Veterans General Hospital
1997-1998	<b>Amzhong Who's Who Award</b> Outstanding Academic Achievement, USA
1997	<b>Le Lauréat</b> Neurology & Psy Association of France

## Major Research Interests:

1. Repair of spinal cord and nerve roots after trauma
2. Neural regeneration and trophic factor

## Publications:

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3. Shoung HM, Cheng H\*, Lee LS, Wu ZA, and Ho DMT. Animal study on intercostals neurotization in avulsion brachial plexus injury. **J of Surg Asso, ROC** 1990; 22-2: 114-119.
4. Cheng H\*, Wang LS, Pan HC, Shoung HM, and Lee LS. Diaphragm pacing for the ventilatory support of the quadriplegic patients with respiratory paralysis. **Chinese Medical J (Taipei)** 1992; 49: 116-22.
5. Cheng H\*, Almstrom S, and Olson L. Fibrin glue used as an adhesion agent in

CNS tissues. **J of Neural Transplantation & Plasticity** 1995; 5(4): 233-243.

6. Cheng H\*, Hoffer B, Stromberg I, Russell D, Olson L. The effect of glial cell line-derived neurotrophic factor in fibrin glue on developing dopamine neurons. **Exp Brain Res.** 1995; 104: 199-206.
7. Cheng H\* and Olson L. A new surgical technique that improves proximo-distal regeneration of 5-HT fibers after complete transection of the rat spinal cord. **Experimental Neurology.** 1995; 136: 149-161.
8. Cheng H\*, Cao Y, Olson L. Spinal cord repair in adult paraplegic rats: partial restoration of hind limb function. **Science** 1996; 273, 510-513.
9. Cheng H\*, Shoung HM, Chen KC, Wu ZA, Lee LS. Functional connectivity of the transected brachial plexus after intercostal neurotization in monkeys. **J Comp Neurol.** 1997; 380: 155-163.
10. Olson L and Cheng H\*. Spinal Cord Repair Strategy: Problems and prospects. **J. Spinal Cord Medicine** 1997; 20: 379-382.
11. Cheng H\*, Almstrom S, Gimenez-Llort L, Cheng R, Ogren S, Hoffer B, Olson L. Gait analysis of adult paraplegic rats after spinal cord repair. **Experimental Neurology.** 1997; 148: 544-557.
12. Cheng H\*, Fraidakis M, Blomback B, Lapchak P, Hoffer B, and Olson L. Characterization of a fibrin glue-GDNF slow-release preparation. **Cell Transplant** 1998; 7: 1: 53-61.
13. Olson L, Cheng H\*, Zetterström R, Solomin L, Jansson L, Giménez-Llort L, Hoffer B, Perlmann T. On CNS repair and protection strategies: novel approaches with implications for spinal cord injury and Parkinson's disease. **Brain Research Reviews** 1998; 26: 302-305.
14. Fraidakis M, Klason T, Cheng H\*, Olson L, and Spenger C. High-Resolution MRI of Intact and Transected Rat Spinal Cord. **Experimental Neurology** 1998; 153: 299-312.
15. Huang MC, Kubo O, Tajika Y, Cheng H\*, Huang CI, Lee LS, and Takakura K. Detection of Mammosomatotrophs in Paraffin-Embedded Specimens of Various Pituitary Adenomas. **Chin Med J (Taipei)** 1999; 62:845-851.
16. Shu CH\*, Cheng H, Lirng JF, Chang FC, Chao Y, Chi KH, Yen SH. Salvage Surgery for Recurrent Nasopharyngeal Carcinoma. **Laryngoscope** 2000; 110: September.
17. Cao Y\*, Veitonmaki N, Keough K, Cheng H, Lee LS, Cao Y, and Zurakowski D. Elevated Levels of Urine Angiostatin and Plasminogen/ Plasmin in Cancer Patients. **International Journal of Molecular Medicine** 2000; 5: 547-551.
18. Tzeng SF\*, Cheng H, Lee YS, Wu JP, Hoffer B, and Kuo JS. Expression of Neural Cell Adhesion Molecule in Spinal Cords Following a Complete Transection. **Life Sciences** 2001; 68: 1005-1012.
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22. Hsieh JC, Cheng H\*, Hsieh HM, Liao KK, Wu YT, Yeh TC, Ho LT. Loss of Interhemispheric Inhibition on the Ipsilateral Primary Sensorimotor Cortex in Patients with Brachial Plexus Injury: an fMRI Study. **Ann Neurol** 2002; 51:381-385.
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55. P-H Lin, T-Y Chuang, K-K Liao, H Cheng, Y-S Shih. Functional Recovery of Chronic Complete Idiopathic Transverse Myelitis after Administration of Neurotrophic Factors. **Spinal Cord**, 2006 44, 254-257.
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Spinal Cords. **Biochemical and Biophysical Research Communications**, 357 (2007) 1-7.

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59. Chiang-Wei Chou, Wen-Cheng Huang, Yang-Hsin Shih, Liang-Hsung Lee, Chantelle Wu, Henrich Cheng\*. Occult occipital condyle fracture with torticollis and normal neurological function: case report and literature review. **Journal of Clinical Neuroscience**, First accepted on March 2, 2007; doi:10.1016/j.jocn.2007.03.014.

60. Henrich Cheng, Yi-Cheng Huang, Pei-Teh Chang, Yi-You Huang\*. Laminin-incorporated nerve conduits made by plasma treatment for repairing and spinal cord injury. **Biochemical and Biophysical Research Communications**, 357 (2007) 938-944

61. May-Jywan Tsai, Ching-Feng Weng, Song-Kun Shyue, Dann-Ying Liou, Chien-Hung Chen, Chuan-Wen Chiu, Tsu-Hsuan Yang, Hsu-An Pan, Roanna I-Hsin Liao, Huai-Sheng Kuo, Ming-Chao Huang, Wen-Cheng Huang, Barry J. Hoffer, and Henrich Cheng\*. Dual Effect of Adenovirus-Mediated Transfer of BMP7 in Mixed Neuron-Glial Cultures: Neuroprotection and Cellular Differentiation. **Journal of Neuroscience Research**, 85: 2950-2959 (2007)

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### Conference Papers:

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